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Little is known about the influence of physician characteristics on breast cancer care, or the interaction of physician and patient characteristics on this care. The primary aim of this study is to investigate how physician gender influences care for breast cancer patients. Secondly, we wish to examine the independent and joint influences of physician characteristics, including geographic region, race, experience, and specialty, and patient characteristics including race, age socioeconomic status, comorbidities, and mobility on breast cancer care.

We are conducting a fractional experiment where two medical scenarios are produced for videotape of women presenting breast cancer care. Sixteen versions of each videotape maintain the same clinical information while varying only those patient features as part of the experimental design. Pairs of females and male physicians matched on specialty, race, and experience are recruited from three geographic areas to view one version of each videotape and state their management practices of female and male physicians independent of other physician and patient characteristics, as well as the interactive influence of these factor on patient care. The results of this study will define variation in breast cancer care and can lead to new strategies to target specific groups of physicians to improve breast cancer care.

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PI - Signature 10/28/96
Date

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5.0 INTRODUCTION

5.1 Specific Aims

Recent data have shown that physician sex is a strong predictor of health services that women receive as patients. This study will build on our previous work on patient characteristics that are factors to appropriate diagnosis and treatment of breast cancer in women aged 65 and older. The primary question of focus for this study is:

1. How does physician gender influence the diagnosis and treatment of breast cancer in women?

Secondary questions to be explored in the analysis are:

2. What are the independent and joint influences of physicians' race, geographic location, practice specialty and age on (a) diagnosis, (b) treatment recommendations, and (c) referral patterns?

3. What are the independent and joint influences of patient age, race, socioeconomic status, comorbidity, and frailty on (a) diagnosis, (b) treatment recommendations, and (c) referral patterns for suspected and diagnosed breast cancer?

4. Can any variations in diagnosis and treatment patterns be explained by the interaction of patient and physician characteristics?

5.2 Fractional Factorial Experiment

In order to assess the independent effect of provider characteristics on patient management, we require a method to hold constant the clinical characteristics of the patient and vary only those aspects of the patient that we wish to assess. We have developed a unique experimental design, where clinical "patients" are developed for videotape and enacted by actors to simulate patient-physician encounter. Versions of each videotape are produced that maintain the same clinical information while varying those patient features as part of the experimental design.

In each of two medical scenarios, we shall investigate five patient factors: age, race, socioeconomic status, comorbidity and mobility. For simplicity of analysis, each factor is dichotomized. The patients enacted on videotape are either 65 or 80 years of age, and either black or white. Socioeconomic status is either upper-level or lower-level, as expressed by a complex of characteristics, including dress, idioms of speech, and coverage by Medex versus Medicaid health insurance. Comorbidity is dichotomized as a patient free of chronic illness, or one with stable hypertension and diabetes on oral medication. Mobility is defined as either no

disabling condition, or frailty as a woman with osteoarthritis of the knees requiring the use of a walker.

The five patient characteristics are capable of 32 combinations, which would constitute a full factorial design. Using the principle of fractional factorial design (Cochran and Cox, 1957; Kirk, 1982) we have selected half that many combinations, balanced so that each factor or combination of two factors occurs half the time with each of the other factors.

Each of the 16 "characters" enacts two scenarios. In the first scenario, the patient presents with a question of a new breast mass, seeking diagnostic evaluation. In the second scenario, the patient presents with a confirmed .8 cm carcinoma by excisional biopsy and seeks recommendations for completion of diagnostic evaluation, primary and adjuvant therapies.

5.3 Physician Characteristics and Study Population Selection

The character of the physician on videotape is invariant across all patients and scenarios. What we plan to vary by stratification and pairing are the characteristics of the physicians to whom the tapes are shown. Ideally we would have chosen a factorial design to investigate physician factors. However, it is unlikely that we will be able to fill all cells, especially with black physicians. Therefore, we chose to use matched pairs of male and female physicians to study our primary variable of interest, matching to control for other variables.

The highest stratum of the sample is geographic location. Three sites have been selected, each centered in a metropolitan area with a substantial population of female and minority physicians. Within each site, 32 female physicians will be recruited. Black physicians will be over-sampled, in order to provide enough statistical power to make inferences about those factors.

For each female physician agreeing to the experiment, a matching male physician will be recruited. The matching man will view the same videotape scenarios as his female counterpart, in an independent session. The matching criteria will be race, age, locale and specialty. Within each site, the 32 matched pairs of physicians will be assigned at random to view one of 16 pairs of videotapes, in such a way that each videotape pair is used exactly twice per site. Thus we shall combine a half-factorial on 5 patient characteristics with equal numbers of matched female and male physicians in each of the 3 locales, and stratification on the physician's secondary characteristics.

The population from which the sample will be selected has been deliberately chosen to maximize the generalizability of inferences while retaining a feasible research design. It consists of medical oncologists, general surgeons and surgical oncologists, specialists who provide diagnostic and therapeutic services for women with breast cancer. In the previous study gynecologists and radiation oncologists were also included in the sampling frame. They are now excluded for two reasons. Gynecologists in major metropolitan areas rarely perform breast biopsies and no longer perform mastectomies. Experience from our previous investigation

revealed that only six gynecologists were eligible out of 223 (< 3%) who were screened for eligibility. Radiation oncologists were excluded, as they reported in the previous study that the first case was atypical of the patients they see in clinical practice. Removing these groups will maintain our generalizability while improving the ability to find eligible physicians to enroll as subjects. We have chosen to maintain these strict inclusion/exclusion criteria in order to have a uniform sample and increase our generalizability to this group of providers who make most decisions regarding breast cancer care. We have also maintained the exclusion of physicians who received their medical school training outside the United States, as the issues of physician and patient gender and race and their interaction may be very different for those physicians who received their medical training in different countries and cultures.

The 3 statistical metropolitan areas, Detroit, Atlanta, and San Francisco/Oakland, were chosen to represent areas with more women and black physicians in their areas, and to represent geographic areas with high (San Francisco/Oakland), moderate (Detroit), and low (Atlanta) utilization of breast conserving surgeries (Nattinger 1992, Farrow 1992).

6.0 BODY

The work performed for year 2, months 13-24, will discuss 6.1) Instrument Revision, 6.2) Sampling and Recruitment Strategies, 6.2.1) Dataset Development, 6.3) Consultants, 6.4) Training of Field Interviewers, 6.4.1) Training Sessions, 6.4.2) Training Agenda, 6.4.3) Site Visits, 6.5) Interviews, 6.5.1) Refusal Rate, 6.6) Data Management, 6.6.1) Quality Assurance 6.6.2) Programming, 6.7) Other Preparatory Activities, 6.8) Planned Activities for Project Year 03, 6.8.1) Field Interviews, 6.8.2) Site Visits, 6.8.3) Database Development, 6.8.4) Data Entry, 6.8.5) Initial Data Analysis, and 6.8.6) Presentation of Results.

6.1 Instrument Revision (Task 1)

The Interviewer-Administered Questionnaire has been revised in several ways in order to improve the overall quality of the interviews. The revisions were based on a review of the completed interviews and specific problems encountered by the interviewers. The following issues have been addressed. Appendix 1 contains a detailed description of the changes made to the instrument. Note that no questions were directly changed, but rather instructions to interviewers regarding the questions were modified.

1) Presentation Format: Revisions were made to the overall format of the instrument in order to improve ease of administration of the questionnaire.

2) Interviewer Instructions: Revisions were made to interviewer instructions in order to clarify and standardize instructions to the interviewer.

3) Probes: Revisions were made to the interviewer instructions in order to clarify probes and to ensure accurate probing by the interviewers.

4) Skip Patterns: Revisions were made to the interviewer instructions in order to clarify skip patterns for interviewers.

6.2 Sampling and Recruitment Strategies (Task 2/5/7/9)

The primary aim of this study is to investigate how physician gender influences care for breast cancer patients. We have found that in all three geographic areas there are a limited number of women that meet the eligibility requirements for this study. There are however, sufficient numbers of men that meet the eligibility requirements in all three locations. Upon realizing that it was going to be challenging to recruit eligible females for the study, we have made our first priority to recruit and interview eligible female physicians. We will then concentrate on finding matches for all of the completed interviews.

The secondary aim in this study is to investigate the joint and independent effects of physician race and subspecialty. As information about physician race is not obtainable by any commercial listing of physicians our consultants have developed lists of black physicians in their communities, which are being used to recruit black physicians. Our first priority however is to recruit females, given our difficulties in finding females who meet the study requirements.

6.2.1 Dataset Development

The initial dataset, drawn from tapes from each state licensing board for census in the SMSSs for the three regions, included male and female doctors, with specialties of general surgeon, medical oncologist, and internal medicine. A portion of the dataset arrived with specialties indicated, but the majority of cases did not indicate a specialty. No phone numbers were provided. The dataset was assigned ID numbers for each case and randomized. Phone numbers were searched for the first 200-300 names per site using a national telephone listings from CD-ROM. Batches were drawn for each site and letters sent. Telephone screening was initiated, and phone number research continued.

The results of the first three hundred cases screened were that 1) all internal medicine cases proved ineligible because they had provided no breast cancer care/chemotherapy, and 2) numbers of women were almost nonexistent. The assumption that some internists would in fact prove to be oncologists proved false. These cases were assigned "non-sample" status, as they proved to be uniformly ineligible and therefore unusable.

The assumption that a dataset of 30,700 cases would yield 96 eligible female cases reasonably *quickly* without further division of the dataset bore further examination. First, all cases were assigned a gender code. The results are as follows:

Female/Male/Combined and By Group/Site

Overall Totals

Total	30772
Male	23678
Female	7094

Totals By Site

Site	Georgia (1)	Michigan (2)	California (3)
Total	8249	9560	12963
Male	6400	7558	9720
Female	1849	2002	3243

Totals By Group

Group	GS	IM	ON	Blank	Other
Total	1009	1252	185	28299	27
Male	912	1054	161	21528	23
Female	97	198	24	6771	4

Totals By Group and Site

Site = Georgia (1)

Group	GS	IM	ON	Blank	Other
Total	304	13	72	7860	0
Male	289	12	62	6037	0
Female	15	1	10	1823	0

Site = Michigan (2)

Group	GS	IM	ON	Blank	Other
Total	346	857	69	8261	27
Male	316	744	60	6415	23
Female	30	113	9	1846	4

Site = California (3)

Group	GS	IM	ON	Blank	Other
Total	359	382	44	12178	0
Male	307	298	39	9076	0
Female	52	84	5	3102	0

GS = General Surgery
IM = Internal Medicine
ON = Oncology
Blank = No Specialty Listed
Other = Other Specialties (other than the above listed specialties)
All totals are based on the data as it appeared on 6/21/96.

With more than three times as many male as female physicians, and only 121 female cases with usable specialty codes, the decision was made to ascertain specialty codes for all blank female cases first. From that point forward the female cases would be screened and scheduled first, on the assumption that it would be easier to match them with males from the larger pool than vice versa. The 1994 AMA Directory of Physicians in the United States was obtained, and all female physicians without specialty codes were looked up and assigned them. Over 98% of the blank female cases were rendered ineligible due to wrong specialty. After screening, the total numbers of potentially eligible female GS and ON cases for each site were as follows:

GA	45
MI	60
CA	75

Further screening yielded more difficulties with these cases. Many general surgeons proved ineligible because they had not performed procedures required for eligibility. Some cases had moved or retired, and some were untraceable for phone numbers with only the original dataset and AMA information. Some were also eliminated due to ethnicity.

Further steps were taken both to 1) increase the overall numbers of potential eligible female cases for each site, and 2) obtain more recent phone and address information for such cases as could be located. A CD-ROM dataset from the American Board of Medical Specialties proved helpful in both areas, since the information it contained was correct as of June 30, 1996. Some new cases were identified for each site. However, the total numbers of potentially eligible female cases remained below the target, given attrition due to lack of performed procedures, lingering problems with phone numbers, and attrition due to ethnicity or site of medical education (non-US).

The next step was to increase the area from which names could be drawn. The decision was made to increase the area codes for each site as follows:

GA	404, 770	added 912, 706
MI	818, 313	added 517, 616
CA	415,510	added 408, 916, 707

The yield for California was sufficient that the target now appears reachable. However, these searches added only 15 cases to Michigan and 1 to Georgia.

Additional searches underway are using the National Cancer Institute Information Associates Program. It lists all affiliated hospitals, practices, programs and physicians. Also, state health departments are forwarding lists of hospitals in each state, which will be contacted individually to obtain rosters of surgeons and oncologists. It is expected that a much larger geographical area will have to be used to generate sufficient numbers for Georgia and Michigan.

Given that each of the three geographic locations were chosen for their rate of breast conserving surgery it was necessary to pick alternates sites with similar rates of breast conserving surgery. By referring back to the study of the use of breast conserving surgery by Nattinger (1992) to locate alternate sites, we found that Chicago had similar rate of breast conserving surgery to Detroit, and Alabama, North Carolina, or South Carolina had similar rates to Atlanta. A follow-up study recently published by Nattinger (1996) found that there has been minimal change in the overall use of breast conserving surgery from 1986-1990. Therefore, the alternate sites are similar for the purposes of this study.

Initial searches indicate that Chicago (area code 312) would yield 33 potentially eligible female cases. North Carolina yielded 69 potentially eligible cases; Alabama 17, Tennessee 29, and South Carolina, 17. Using the numbers of potentially eligible female physicians and considering costs involved in interviewers traveling to the alternate cities, it was decided that Chicago be used as an alternate for Detroit, and Alabama and Tennessee as alternates for Atlanta. For each of these alternate sites, we will recruit only female physicians. Being that there are sufficient numbers of eligible men in both Detroit and Atlanta, it is not necessary to recruit men from these alternate sites.

Therefore, given that a) we are stating that for the purposes of this study these areas are similar in rates of breast conserving surgery and b) the increased costs of going outside our original areas, we will match the female physicians from the alternate sites to male physicians from Detroit or Atlanta.

Finally to ensure that our databases have identified all eligible women, we are employing a "snowball" technique of recruitment from our subjects' circles of colleagues. At the end of the interview, subjects are asked for the names of other physicians in the area, specifically surgeons who have performed breast biopsies and mastectomies in the last five years, or medical oncologists who have provided breast cancer care in the last five years. This techniques initially identified a few women not listed on any other source, but has quickly verified the exhaustive nature of our searches by identifying only previously known female physicians in these specialties.

6.3 Consultants

During year 2 of this project, we have continued to use the same three consultants, one from each of the geographic locations to assist with the project. Laura Essermann, MD from California, Bruce McCarthy MD, MPH from Detroit, and Christopher Lockhart, MD, from Atlanta.

All consultants have preformed the following tasks:

1) Minority and female recruitment -- Each consultant has prepared lists of both female and black physicians in their communities, which has helped in recruitment of eligible providers.

2) Information on local practice patterns -- The consultants have provided valuable information on certain practice patterns in their communities. For example, in California the estrogen/progesterone receptor test is presented in a different format in California, than it is presented in this study. Also, they have provided information surrounding the recent FDA approval and local marketing practices and use of the high definition ultrasound test.

3) Co-signing introductory letters -- Consultants have continued to sign introductory letters on their own stationary along with the Principal Investigator and Co-Principal Investigators signatures.

4) Contacting refusers -- The Consultants have contacted refusers and personally asked them to participate in the study.

6.4 Training of Field Interviewers (Task 3)

6.4.1 Training Sessions

To date there have been three interviewer training sessions, which occurred in December 1995, June 1996, August 1996. The first interviewer training was held Monday, December 11, 1995 through Wednesday, December 13, 1995 in Boston, MA. At this session there were three interviewers trained; Rebecca Vaughn, B.A. from Atlanta, Susan Sheffield, M.A. from San Francisco, and Eric Blumberg, from Detroit. The second interviewer training was held on Thursday June 27, 1996 through Friday June 28, 1996 in Boston. This training occurred when Eric Blumberg left the project and Sabrina Black was hired to take over his position interviewing in Detroit. The third interviewer training was held on Wednesday August 21, 1996 through Thursday August 22, 1996 in Boston. This training occurred when four more interviewers were hired to ensure maximum flexibility with physician interviewing schedules. The four interviewers were trained were Deborah Dahn, B.A. from Detroit, Lisa Meyer, B.A. and Eric Riles, B.A. from Atlanta, and Sarah Bates, M.A. from San Francisco.

6.4.2 Training Agenda

Each of the training seminars were conducted by project staff from New England Research Institutes and Boston University Medical Center. See Appendix 2 for schedules of each of the training sessions. Each training session consisted of the following components: 1) Project Introduction. This section included a general introduction to the project and an introduction to breast cancer treatment issues and terminology; 2) Interviewer Training. This section included an introductory video, interviewers manual and discussion about confidentiality; 3) Instrument Training. This section included viewing the project video, reviewing the interviewing structure, and a review of the instruments, discussing each question individually; 4) Mock Interviews. Each interviewer observed one interview; 5) Practice Interviews. Each interviewer completed 2 practice interviews with 'mock subjects' and was given feedback and an opportunity to ask questions; 6) Conclusion. The training ended with a discussion about the quality assurance plan, communication details between interviewer site and New England Research Institutes, and question/answer period.

As a part of the training each interviewer also completed a practice interview with the consultant in their home location, and they each had a practice interview with a physician who was not eligible, while both the interviewer and physician were unaware that the interview was not going to be included in the study.

6.4.3 Site Visits

There has been one in person site visit to California conducted, where two interviews were personally observed. In the site visit the interviewer was personally observed during two interviews with physicians, provided with feedback and given the opportunity to clarify any questions about the instrument.

6.5 Interviews (Tasks 6/8/10)

Following are the numbers of completed and scheduled interviews for the end of September 1996, by gender, race and subspecailty for all three locations separately and together. See Appendix 3 for a breakdown of individual interviews by states.

Our projected goal for the end of the year 2 was 40 interviews at each site. We have met this goal in scheduled and completed interviews in California, where we were able to find sufficient female physicians locally who are eligible to participate. We also met our goal of recruiting 60 female physicians by the end of year 2. We did not meet out goals of 40 physicians in each of Atlanta and Detroit, due to difficulties outlined in 6.2, in identifying eligible female physicians.

Approximately one third of physicians recruited are in medical oncology and two thirds in surgery. This breakdown will provide approximately 64 medical oncologists and 128 surgeons, and sufficient power to perform analyses by physicians specialty type, with the ability to detect at least a 18-24% difference between physician specialty with >80% power (see Appendix 4).

Unfortunately the number of African American physicians recruited is small, and will result in lower power for analyses by physician race. We believe that our multiple recruitment methodologies have identified all eligible African American physicians in areas of recruitment. If 10% of the sample is African American, we will be able to detect a 22-36% differences by physicians race with 80% power. (See Appendix 4).

6.5.1 Refusal Rate

To date there have been 23 physicians who have refused to participate in the study, which gives us a 80% participation rate. Of these, there are 9 males and 0 females in San Francisco, 1 male and 3 females in Atlanta, and 5 males and 5 females in Detroit. Currently our consultants are placing personal phone calls to the eligible physicians to recruit them into the study. With an expected rate of recruitment conversion at 50% we expect to recruit an additional 1-2 females in Atlanta and 2 females in Detroit.

Totals for Site 1 -- San Francisco, California

	Scheduled	Interviewed	Total
Gender			
Males	9	2	**11**
Females	11	19	**30**
Total	**0**	**21**	**41**
Race			
African American	0	1	1
Caucasian	20	20	**40**
Total	**20**	**21**	**41**
Specialty			
Medical Oncology	7	4	**11**
General Surgery	13	17	**30**
Total	**20**	**21**	**41**

Totals for Site 2 -- Detroit, Michigan

	Scheduled	Interviewed	Total
Gender			
Males	4	5	**9**
Females	8	10	**18**
Total	**12**	**15**	**27**
Race			
African American	0	0	**0**
Caucasian	12	15	**27**
Total	**12**	**15**	**27**
Specialty			
Medical Oncology	4	3	**7**
General Surgery	8	12	**20**
Total	**12**	**15**	27

Totals for Site 3 -- Atlanta, Georgia

	Scheduled	Interviewed	Total
Gender			
Males	2	11	**13**
Females	3	9	**12**
Total	**5**	**20**	**25**
Race			
African American	2	5	**7**
Caucasian	3	15	**18**
Total	**5**	**20**	**25**
Specialty			
Medical Oncology	2	8	**10**
General Surgery	3	12	**15**
Total	**5**	**20**	25

Totals for all Locations

	Scheduled	Interviewed	Total
Gender			
Males	15	18	**33**
Females	22	38	**60**
Total	**37**	**56**	**93**
Race			
African American	2	6	**8**
Caucasian	35	50	**85**
Total	**37**	**56**	**93**
Specialty			
Medical Oncology	13	15	**28**
General Surgery	24	41	**65**
Total	**37**	**56**	**93**

6.6 Data Management

6.6.1 Quality Assurance

All instruments and data forms are being checked on an ongoing basis for completion, accuracy and legibility of the interviews and instrument. A quality review of audiotapes from every interview is being done by two people. The Field Supervisor, Dennis Cohen, does the logistical editing of all audiotapes and the Project Manager, Michelle Mancuso, reviews the tapes for medical/scientific accuracy. To date 98% of the interviews that have been reviewed are acceptable for inclusion in the study.

A problem coding log, in which all "other" category responses and specific circumstances are recorded has been complied and is being maintained. All feedback from the Project Manager is given to Field Supervisor who then reports all feedback to each individual interviewer. In addition, weekly memos of problems and concerns of interviewers are being composed and sent out to all interviewers. The Principal Investigator monitors this process on a regular basis.

6.6.2 Programming

Programming has begun on all three instruments; the screener, the self-administered questionnaire, and the interviewer administered questionnaire. We are beginning to test for data entry.

6.7 Other Activities

Institutional Review Board -- Approval has been renewed from the Boston University Medical Center Hospital IRB (Appendix 5).

6.8 Planned Activities for Project Year 03

6.8.1 Field Interviews

We plan to have all interviews completed by June 1997. We anticipate that we will be able to meet this goal given that we have completed much of the recruitment of female physicians. Finding matching males for each female subject will be considerably less time intense given the larger pool of potential subjects.

	Months
In - person interviews site 1	
a) 40 interviews completed	24 - 27
b) 56 interviews completed	27 - 30
c) 64 interviews completed	30 - 33
In-person interviews site 2	
a) 40 interviews completed	24 - 27
b) 56 interviews completed	27 - 30
c) 64 interviews completed	30 - 33
In-person interviews site 3	
a) 40 interviews completed	24 - 27
b) 56 interviews completed	27 - 30
c) 64 interviews completed	30 - 33

6.8.2 Site Visits

Additional site visits are planned for Detroit and Atlanta within the first three months of Year 3 of the project. The goal of each visit will be to observe at least two interviews completed by each local interviewer. Feedback will be provided after each observed interview. Interviewers will be provided an opportunity to clarify any questions with the site visitor.

6.8.3 Data Base Development

Programming of all three instruments will be completed. Variables will be developed based upon the major independent and dependent variables defined in our previous study, with necessary modification for

changes in the current questionnaire on preparation of the initial analyses in July 1997.

6.8.4 Data Entry

With data collection scheduled for completion in June 1997, we anticipate that 90% of all pairs of data will be reviewed, coded and entered by July 1997.

6.8.5 Initial Data Analysis

We plan to begin initial analyses with at least 90% of all data pairs coded and entered by July 1997.

We plan the following initial analysis of the data towards a presentation in October 1997 at the Department of Defense Breast Cancer Research Program.

Case I - Presentation of Possible Breast Mass

The two major outcome variables of interest will be the 1) probability estimate of breast cancer and 2) recommendation of some form of tissue analysis, including fine needle aspiration biopsy, core biopsy or open biopsy. Initial analysis will be paired-tests to identify if physician gender, matched for all other variables including geographic area, race, specialty and years in training are associated with physicians' estimates of likelihood of breast cancer and decision to obtain tissue analysis. Second, multiple regression and logistic regression models will be developed to predict the probability estimate of breast cancer and recommendation for tissue analysis. Variables included in each model will be the five patient characteristics (age, race, specialty, socio-economic status, mobility and comorbidities) and four physician characteristics (gender, race, subspecialty, and years of practice). Initially no interaction will be included. We shall use the CATMOD implementation of MLLR (SAS, 1988) because it permits us to analyze the responses of the male and female members of each pair as a joint outcome and to build models using the factorial structure of the independent variables in a convenient, flexible programming language.

Case II - Stage IIA Breast Cancer

Initial analysis will look at the following outcome variables:

1) Use of axillary node dissection
2) use of testing to investigate for metastatic spread
3) use of full primary therapy
4) use of breast conserving therapy
5) use of tamoxifen
6) use of chemotherapy

For each of these 6 variables, initial matched pair analyses will be performed to investigate if physician gender is associated with any preferred physician recommendation.

Next logistic regression models will be developed for each of these 6 dependent variables, to look at the independent effect of each of the 5 patient and 4 physicians variables. Again we shall use the CATMOD implementation that allows for the paired nature of our data. These analyses will for the basis of the presentation to the Department of Defense Breast Cancer Research Program in October 1997.

6.8.6 Presentation of results

Develop presentation for October 1997 Department of Defense Breast Cancer Research program.

7.0 Conclusion

We have made substantial progress in the past year. We did meet our goal of 40 interviews in San Francisco. We did not meet our goal of 40 completed interviews in Detroit and in Atlanta, due in part to difficulties outlined above in finding sufficient numbers of eligible women physicians to recruit. We have developed and outlined a process that will allow us to reach our recruitment goals. To date we have recruited 93 physicians. This includes 60 women, 100% of our goal of female physicians for year 2, and 62.5% of the total needed female subjects. We have outlined a realistic plan for recruiting and interviewing the remaining women, and given the large pool of available male physicians, do not anticipate difficulty in findings matching subjects.

Our goals for year 3 include:

1) Completion of interviews for all physicians.
2) Development of data management system.
3) Initial data analysis.
4) Presentation of preliminary analyses at Department of Defense Cancer Research Meeting.

8.0 **REFERENCES**

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9.0 **APPENDICES**

Index of Appendices

1) Changes to the Interviewer-Administered Questionnaire Question by Question
2) Schedule for Training of Interviewers
3) Physicians Recruited by State
4) Precision and Power of Experimental Design
5) Institutional Review Board Approval and Consent Form

Physician Decisions in Breast Cancer Care
Changes to the Interviewer-Administered Questionnaire
Question by Question

Case 1, Evaluation, Q1, part A

Original	If 0 is completely unlikely and 100 is completely likely, what the chances that the patient has [DIAGNOSIS] ? [Note to interviewer: Chances do not have to equal 100% but must not exceed 100%.]
Revised	If 0 is completely unlikely and 100 is completely likely, what are the chances that the patient has [INSERT DIAGNOSES CHOSEN IN QUES. 1]? [NOTE: CHANCES DO NOT HAVE TO EQUAL 100% BUT SHOULD NOT EXCEED 100 %. PROBE ONLY ONCE: "Doctor, here, although the chances do not have to equal 100%, they should not exceed 100%."]
Rationale	To clarify instructions.

Case 1, Evaluation, Q2- Q4, part B

Original	What is the primary information about this case that led you to consider **[DIAGNOSIS]?[PROBE ONCE: Anything else?]**
Revised	What is the primary information about this case that led you to consider **[INSERT DIAGNOSES CHOSEN IN QUESTION 1]? [PROBE ONCE:** "Anything else?]
Rationale	To clarify instructions.

Case 1, Evaluation, Q5b

Original	What tests would you order or wish to see the results of at the first visit, understanding you could order more tests after the results are known? (NOTE: IF ANSWER **EXCISIONAL/INCISIONAL BIOPSY**, ASK" Prior to open biopsy, would you perform any other tests or x-rays?" IF YES, GO TO 5b; IF NO, GO TO PAGE 9)
Revised	**[IF YES]** What tests would you order or wish to see the results of at the first visit, understanding you could order more tests after the results are known.? **[NOTE: IF BIOPSY REQUESTED, ASK, "What kind of biopsy?" IF ANSWER EXCISIONAL/INCISIONAL BIOPSY, ASK,** "Prior to open biopsy, would you perform any other tests or x-rays?" **IF YES, RECORD IN 5b. IF NO, GO TO PAGE 10, PATIENT MANAGEMENT.]**
Rationale	To improve ease of administration. To clarify instructions.

Case 1, Evaluation, Q6

Original	There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[TEST]** for this patient? **[IF NOT SPECIFIC PROBE: "WHAT DO YOU MEAN", ETC.]**
Revised	There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering [INSERT TESTS GIVEN IN QUESTION 5b] for this patient? [RECORD ONE RESPONSE FOR EACH TEST.] [IF NOT SPECIFIC, PROBE: "What do you mean?",
Rationale	To improve ease of administration. To ensure accurate probing.

Case 1, Evaluation, Q7

Original	Taking these test results into account, would you order additional diagnostic tests or x-rays? 1. No, would not order **(GO TO QUESTION 11)** 2. Yes, would order
Revised	Taking these tests results into account, would you order additional diagnostic tests or x-rays? 1. No, would not order **[IF NO, GO TO QUESTION 11]** 2. Yes, would order **[IF YES, GO TO QUESTION 7b]**
Rationale	To clarify skip pattern.

Case 1, Evaluation, Q7b

Original	7b.(IF YES) What would you order?
Revised	**[IF YES]** What would you order? **[NOTE: IF BIOPSY REQUESTED, PROBE**: "What kind of biopsy?" **IF ANSWER EXCISIONAL/INCISIONAL BIOPSY, ASK**: "Prior to open biopsy, would you perform any other tests or x-rays?"] **[IF YES, RECORD IN 7b. IF NO, GO TO QUESTION 11.]**
Rationale	To clarify skip pattern

Case 1, Evaluation, Q8

Original	There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[TEST]** for this patient? **[IF NOT SPECIFIC PROBE: "WHAT DO YOU MEAN", ETC.]**
Revised	There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[INSERT TEST]** for this patient? **[IF NOT SPECIFIC, PROBE:** "What do you mean?", **ETC.] [RECORD ONE RESPONSE FOR EACH TEST.]**
Rationale	To clarify probe. To ensure accurate probing.

Case 1, Evaluation, Q9

Original	Taking these test results into account, would you order additional diagnostic tests or x-rays?
Revised	Taking these test results into account, would you order additional diagnostic tests or x-rays? 1. No, would not order **[IF NO, GO TO QUESTION 11]** 2. Yes, would order **[IF YES, GO TO QUESTION 9b]**
Rationale	To clarify skip pattern.

Case 1, Evaluation, Q9b

Original	What would you order?
Revised	**[IF YES]** What would you order? **[NOTE: IF BIOPSY REQUESTED, PROBE**: "What kind of biopsy?" **IF ANSWER EXCISIONAL/INCISIONAL BIOPSY, ASK**: "Prior to open biopsy, would you perform any other tests or x-rays?"] **[IF YES, RECORD IN 9b. IF NO, GO TO QUESTION 11.]**
Rationale	To clarify skip pattern.

Case 1, Evaluation, Q10

Original	There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[TEST]** for this patient?
Revised	There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[INSERT TEST]** for this patient? **[IF NOT SPECIFIC, PROBE**: "What do you mean?", **ETC.] [RECORD ONE RESPONSE FOR EACH TEST.]**
Rationale	To improve ease of administration. To ensure accurate probing.

Case 1, Evaluation, Q12

Original	If 0 is completely unlikely and 100 is completely likely, what are the chances that the patient has: *[Note to interviewer: Chances do not have to equal 100%, but must not exceed 100%]*
Revised	If 0 is completely unlikely and 100 is completely likely, what are the chances that the patient has : **[INSERT DIAGNOSES CHOSEN IN QUESTION 11B]. [NOTE: CHANCES DO NOT HAVE TO EQUAL 100%, BUT MUST NOT EXCEED 100%. PROBE ONLY ONCE**: "Doctor, here, although the chances do not have to equal 100%, they should not exceed 100%."]
Rationale	To clarify instructions.

Case 1, Patient Management, Q1

Original	What recommendation for evaluation and follow-up would you typically recommend after seeing this patient. **[DO NOT READ CATEGORIES. CHECK ALL THAT APPLY. RESPONDENT CAN NAME MORE THAN ONE.**
Revised	What recommendation for evaluation and follow-up would you typically recommend after seeing this patient? **[DO NOT READ CATEGORIES. CHECK ALL THAT APPLY IN COLUMN 1 OF QUESTION 2b. RESPONDENT CAN NAME MORE THAN ONE, BUT DO NOT PROBE FOR MORE.]**
Rationale	To improve ease of administration. To clarify instructions.

Case 1, Patient Management, Q2

Original	Would you discuss with the patient any alternative recommendation for evaluation and follow-up? 1. NO 2. YES
Revised	Would you discuss with the patient any alternative recommendations for evaluation and follow-up? 1. No **[GO TO QUESTION 3]** 2. Yes **[GO TO QUESTION 2B]**
Rationale	To clarify skip pattern.

Case 1, Patient Management, Q2a

Original	(IF YES) What would be your alternative recommendation?
Revised	**[IF YES]** What would be your alternative recommendation? **[RECORD IN COLUMN 2]**
Rationale	To improve ease of administration.

Case 1, Patient Management, Q3

Original	(If #1 A-H are NO). Would you consider obtaining any type of tissue evaluation at this initial evaluation?
Revised	**[IF #1A-H AND #2A-H ARE NOT CHOSEN, AND NONE OF THESE OPTIONS IS CHOSEN AS A TEST IN QUESTIONS 5B, 7B, OR 9B]** Would you consider obtaining any type of tissue evaluation at this initial evaluation?
Rationale	To standardize instruction. To clarify skip pattern.

Case 1, Patient Management, Q3a

Original	(If #1 A-H are NO). Would you consider obtaining any type of tissue evaluation at this initial evaluation?
Revised	**[IF NO]** What is the single most important reason you would not obtain a tissue evaluation at this point? **[DO NOT READ OPTIONS.] [RECORD ONE RESPONSE ONLY]**
Rationale	To guide probing.

Case 1, Patient Management, Q4

Original	(If #1 A-H or 3b. chosen). There are currently many options for type of tissue evaluation. What is the single most important reason you would choose_____?(read physician's choice A-H or 3b. here)
Revised	**[IF #1A-H OR #2A-H OR 3B CHOSEN, OR IF ANY OF THESE OPTIONS CHOSEN AS A TEST IN QUESTIONS 5B, 7B, OR 9B]** There are currently many options for type of tissue evaluation. What is the single most important reason your would choose _____. **[READ PHYSICIAN'S CHOICE A-H ,3B , 5B, 7B, OR 9B HERE. NOTE, IF BOTH 1A-H AND 2A-H CHOSEN, READ 1A-H.] [DO NOT READ OPTIONS] [RECORD ONE RESPONSE ONLY.]**
Rationale	To standardize instructions. To assure correct reading of option chosen by doctor.

Case 1, Patient Management, Q5

Original	(If IN #1A-C or 3b A NEEDLE BIOPSY WAS CHOSEN, i.e. NEEDLE ASPIRATION, NEEDLE ASPIRATION BIOPSY, STEREOTACTIC CORE BIOPSY) If the biopsy was negative, would you perform an open surgical biopsy?
Revised	**[IF IN #1A-C OR 2A-C OR 3B, A NEEDLE BIOPSY WAS CHOSEN, I.E. NEEDLE ASPIRATION, FINE NEEDLE ASPIRATION BIOPSY, STEREOTACTIC CORE BIOPSY; OR IF ANY OF THESE PROCEDURES CHOSEN AS A TEST IN 5B, 7B, OR 9B.]** If biopsy was negative, would you perform an open surgical biopsy?
Rationale	To assure correct reading of option chosen by doctor.

Case 1, Patient Management, Q11

Original	Suppose this patient had an excisional biopsy which revealed fibrocystic changes with no atypical hyperplasia and with no evidence of malignancy. Would you refer or recommend to this patient the Breast Cancer Chemo-Prevention Trial which would randomize her either to placebo or tamoxifen? 1. NO 2. YES
Revised	Suppose this patient had an excisional biopsy which revealed fibrocystic changes with no atypical hyperplasia and with no evidence of malignancy. Would you refer or recommend to this patient the Breast Cancer Chemo-Prevention Trial which would randomize her either to placebo or tamoxifen? 1. No **[IF NO, GO TO Q11A]** 2. Yes **[GO TO Q12]**
Rationale	To clarify skip pattern.

Case 1, Patient Management, Q11a

Original	(IF NO) What would be your main reason for not recommending this trial? (DO NOT READ OPTIONS)
Revised	**[IF NO]** What would be your main reason for not recommending this trial?**[DO NOT READ OPTIONS] [RECORD ONE RESPONSE ONLY]**
Rationale	To clarify probe.

Case 2, Evaluation, Q1

Original	If you saw this patient in your everyday practice, would you perform any diagnostic tests, x-rays, or operative procedures initially, understanding that you could perform other procedures later?
Revised	If you saw this patient in your everyday practice, would you perform any diagnostic tests, x-rays, or operative procedures initially, understanding that you could perform other procedures later? **[NOTE: RECORD ALL MENTIONED. DO NOT PROBE FOR MORE. IF TREATMENTS LIKE MASTECTOMY OR LUMPECTOMY ORDERED, PROBE:,** "Dr., here we would like to know if you would to perform any diagnostic tests or x-rays at this point ." **IF DR INSISTS ON ORDERING NOW, RECORD AS "NO" AND GO TO PATIENT MANAGEMENT, PAGE 21.]**
Rationale	To clarify probe. To clarify skip pattern.

Case 2, Evaluation, Q2

Original	There are many reasons for performing tests, x-rays or operative procedures. What would be your single most important reason for performing **[TEST]** for this patient? **[IF NOT SPECIFIC, PROBE: "WHAT DO YOU MEAN", ETC.]**
Revised	There are many reasons for performing tests, x-rays or operative procedures. What would be your single most important reason for performing **[INSERT TEST]** for this patient? **[RECORD ONE RESPONSE FOR EACH TEST.] [IF NOT SPECIFIC, PROBE:** "What do you mean?", **ETC.]**
Rationale	To clarify probe.

Case 2, Evaluation, Q3

Original	Taking these test results into account, would you perform additional diagnostic tests, x-rays or operative procedures at this point to determine your definitive management plan? **[NOTE: IF R OFFERS A TREATMENT, PROBE FOR DIAGNOSTIC TESTS, X-RAYS OR OPERATIVE PROCEDURES.]**
Revised	Taking these tests results into account, would you perform additional diagnostic tests, x-rays, or operative procedures at this point to determine your definitive management plan? **[NOTE: RECORD ALL MENTIONED. DO NOT PROBE FOR MORE. IF TREATMENT LIKE MASTECTOMY OR LUMPECTOMY ORDERED, PROBE:,** "Dr., here we would like to know if you would to perform any diagnostic tests or x-rays at this point ." **IF DR INSISTS ON ORDERING NOW, RECORD AS "NO" AND GO TO PATIENT MANAGEMENT, PAGE 21.]**
Rationale	To clarify probe.

Case 2, Evaluation, Q4

Original	What would be your single most important reason for performing **[TEST]** for this patient? **[IF NOT SPECIFIC, PROBE: "WHAT DO YOU MEAN", ETC.]**
Revised	What would be your single most important reason for performing **[INSERT TEST]** for this patient? **[IF NOT SPECIFIC, PROBE:** "What do you mean?", **ETC.] [RECORD ONE RESPONSE FOR EACH TEST]**
Rationale	To clarify probe.

Case 2, Evaluation, Q5

Original	Taking these test results into account, would you perform additional diagnostic tests, x-rays or operative procedures at this point?
Revised	Taking these test results into account, would you perform additional diagnostic tests, x-rays or operative procedures at this point. **[NOTE: RECORD ALL MENTIONED. DO NOT PROBE FOR MORE. IF TREATMENT LIKE MASTECTOMY OR LUMPECTOMY ORDERED, PROBE:**, "Dr., here we would like to know if you would to perform any diagnostic tests or x-rays at this point ." **IF DR INSISTS ON ORDERING NOW, RECORD AS "NO" AND GO TO PATIENT MANAGEMENT, PAGE 21**
Rationale	To clarify probe.

Case 2, Evaluation, Q6

Original	What would be your single most important reason for performing **[TEST]** for this patient? **[IF NOT SPECIFIC PROBE: "WHAT DO YOU MEAN", ETC.]**
Revised	What would be your single most important reason for performing **[INSERT TEST]** for this patient? **[IF NOT SPECIFIC, PROBE:** "What do you mean?", **ETC.] [RECORD ONE RESPONSE FOR EACH TEST]**
Rationale	To clarify probe.

Case 2, Patient Management, Q1

Original	What treatment or management plan would you typically recommend after seeing this patient? Please tell me both what primary therapy as well as any adjuvant therapy you would recommend to treat this patient. **[**IF 1ST CHOICE = NODE DISSECTION, HAND R THE RESULTS AND SAY "Here are the results from the axillary node dissection for you to review"]**
Revised	What treatment or management plan would you typically recommend after seeing this patient? Please tell me both what primary therapy as well as any adjuvant therapy you would recommend to treat this patient. **[**IF 1ST CHOICE = NODE DISSECTION, HAND R THE RESULTS AND SAY** "Here are the results from the axillary node dissection for you to review." **RECORD AS FIRST CHOICE AND RE-ASK QUESTION 1. RECORD ANSWERS IN COLUMN 2 AND THEN GO TO QUESTION 3.]**
Rationale	To clarify instructions. To clarify skip pattern.

Case 2, Patient Management, Q5b

Original	What type of specialist would you consult?
Revised	What type of specialist would you consult? **[DO NOT READ OPTIONS. DO NOT PROBE FOR MORE. CHECK ALL THAT APPLY.]**
Rationale	To clarify probe.

Case 2, Patient Management, Q6

Original	(IF NO) Please tell us the most important reason for you. _____ (DON'T READ OPTIONS)
Revised	**[IF NO]** Please tell us the most important reason for you. _____ **[DON'T READ OPTIONS. RECORD ONE RESPONSE ONLY]**
Rationale	To clarify probe.

Case 2, Patient Management, Q7

Original	There has been a lot of debate around when to perform an axillary node dissection. Your preferred choice _____ **was** _____ **was not** to perform the dissection. What was your most important consideration?
Revised	There has been a lot of debate around when to perform an axillary node dissection. Your preferred choice _____ **was** _____ **was not** to perform the dissection. What was your most important consideration? **[THE PREFERRED CHOICE IS THE FIRST MANAGEMENT PLAN: IF AXILLARY NODE DISSECTION CHOSEN IN COLUMN 1, PREFERRED PLAN IS COLUMN 2.] [DON'T READ OPTIONS. RECORD ONE RESPONSE ONLY.]**
Rationale	To clarify probe. To clarify instructions.

Case 2, Patient Management, Q8

Original	Doctors are divided on tamoxifen use. Why **did you/didn't you** offer this treatment as part of your preferred management plan? Please tell me your most important consideration. (DON'T READ OPTIONS)
Revised	Doctors are divided on tamoxifen use. Why **did you/didn't you** offer this treatment as part of your **preferred** management plan? Please tell me your most important consideration. **[THE PREFERRED CHOICE IS THE FIRST MANAGEMENT PLAN: IF AXILLARY NODE DISSECTION CHOSEN IN COLUMN 1, PREFERRED PLAN IS COLUMN 2.] [DON'T READ OPTIONS. RECORD ONLY ONE RESPONSE.]**
Rationale	To clarify probe. To clarify instructions.

Case 2, Patient Management, Q9

Original	Chemotherapy use is also controversial. Why **did you/didn't you** offer this treatment as part of your preferred management plan? Please tell me your most important consideration. (DON'T READ OPTIONS)
Revised	Chemotherapy use is also controversial. Why **did you/didn't you** offer this treatment as part of your **preferred** management plan? Please tell me your most important consideration. **[THE PREFERRED CHOICE IS THE FIRST MANAGEMENT PLAN: IF AXILLARY NODE DISSECTION CHOSEN IN COLUMN 1, PREFERRED PLAN IS COLUMN 2.] [DON'T READ OPTIONS. RECORD ONE RESPONSE ONLY**
Rationale	To clarify probe. To clarify instructions.

Case 2, Patient Management, Q10

Original	Radiation therapy is also a matter of choice. Why **did you/didn't you** offer this treatment as part of your preferred management plan? Again, tell me your most important consideration. (DON'T READ OPTIONS)
Revised	Radiation therapy is also a matter of choice. Why **did you/didn't you** offer this treatment as part of your **preferred** management plan? Again, tell me your most important consideration. **[THE PREFERRED CHOICE IS THE FIRST MANAGEMENT PLAN: IF AXILLARY NODE DISSECTION CHOSEN IN COLUMN 1, PREFERRED PLAN IS COLUMN 2.] [DON'T READ OPTIONS. RECORD ONE RESPONSE ONLY.]**
Rationale	To clarify probe. To clarify instructions.

Case 2, Section on Clinical Trials, Q1

Original	Do you enroll patients in clinical trials? 1 NO (IF NO, GO TO QUESTION 6) 2 YES
Revised	Do you enroll patients in clinical trials? 1. No **[IF NO, GO TO QUES. 6]** 2. Yes **[GO TO QUES. 1B]**
Rationale	

Case 2, Section on Clinical Trials, Q11a/b/c

Original	Would you offer _____ (read physician's answer to Q10a/b/c here) to this patient as a viable treatment option?
Revised	Would you offer _____ **[READ PHYSICIAN'S ANSWER TO QUESTION 10a/b/c HERE]** to this patient as a viable treatment option? **[DON'T READ OPTIONS SHOWN BELOW. RECORD ALL MENTIONED.]**
Rationale	To clarify probe.

Case 2, Section on Clinical Trials, Q14

Original	Suppose that the patient in the second video had 3 of 29 positive lymph nodes. One clinical trial currently available in your area for post menopausal women with Stage II breast cancer investigates whether a dietary fat reduction in conjunction with cytoxan, shows an impact on recurrence. Would you encourage the patient in the second video to enroll in this trial?
Revised	Suppose that the patient in the second video had 3 of 29 positive lymph nodes. One clinical trial currently available in your area for post menopausal women with Stage II breast cancer investigates whether a dietary fat reduction in conjunction with Cytoxan, shows an impact on recurrence. Would you encourage the patient in the second video to enroll in this trial? **[DON'T READ OPTIONS SHOWN BELOW. RECORD ALL MENTIONED.]**
Rationale	To clarify probe.

Case 2, Section on Clinical Trials, Q15

Original	Another trial available in your area for pre or post-menopausal women with 0-3 lymph nodes positive treats participants with 3 doses of adriamycin with cytoxan, with or without Taxol. Supposing she had 3 of 29 lymph nodes positive, would you encourage the patient in the second video to enroll in this trial?
Revised	Another trial available in your area for pre- or post-menopausal women with 0-3 lymph nodes positive treats participants with 3 doses of adriamycin with Cytoxan, with or without Taxol. Supposing she had 3 of 29 lymph nodes positive, would you encourage the patient in the second video to enroll in this trial? **[DON'T READ OPTIONS SHOWN BELOW. RECORD ALL MENTIONED.]**
Rationale	To clarify probe.

Background, Q2

Original	Which of the following would you use to describe yourself? Are you:
Revised	Which of the following would you use to describe yourself? Are you: **[ONE RESPONSE ONLY]**
Rationale	To improve probe.

Background, Q6, instruction only

Original	NA
Revised	**[NOTE: RESPONSE FOR D CANNOT EXCEED RESPONSE FOR C]**
Rationale	To improve accuracy.

Physician Decisions in Breast Cancer Care

Training Schedule: Monday, December 11 - Wednesday, December 13 (2.5 days)

DAY 1 NERI main conference room, 8:30 AM - 5 PM

1) Project Introduction: issues in breast cancer treatment
Karen Freund (1.5 hour)

2) Interviewer Training: a) introductory video
b) interviewer's manual
c) confidentiality
Dennis Cohen (4 hours)

3) Instrument Training: a) project video, interview structure
b) go over instruments
Dennis Cohen, Renee Boss (2 hours)

DAY 2 Boston University Medical Center Hospital, 9 AM - 5 PM
Doctor's Office Building, 720 Harrison Avenue, Suite 1108, Boston

1) Review instruments and entertain questions
Dennis Cohen, Renee Boss (1 hours)
2) Mock (open) interview and entertain questions/comments
Dennis Cohen, Renee Boss (2 hours)
3) Practice interviews by trainees, 2 each
Interviewers and "docs" (4.5 hours)

DAY 3 NERI, 8:30 AM - noon

1) Feedback on practice interviews
2) Communication details (between interview sites and NERI)
3) Quality Assurance plan
4) Questions
Dennis Cohen, Karen Freund, Linda Kasten (3 hours)

Training Schedule for Sabrina Black
Thursday, June 27 and Friday, June 28, 1996

Thursday:

9:30 - 12:30 **Dennis Cohen**

Introduction to the project
Respond to trainees questions (re: pre-training review of the manual)
Discuss communication with NERI
View project videos
Go over the instrument

12:30 - 1:30 **Lunch**

1:30 - 4:30 **Dr. Karen Freund**
Introduction to breast cancer issues

Renee Boss
Terminology

Dennis Cohen and Renee Boss
QA Plan and Confidentiality
Mock Interview

Friday:

9:30 - 12:30 **Renee Boss**
De-brief mock interview
Mock interview with trainee

12:30 - 1:30 **Lunch**

1:30 - 4:30 **Renee Boss and Dr. Karen Freund**
Feedback on trainee's mock interview

Guest Physician
Mock interview with trainee

Renee Boss
Discuss trainee/physician mock interview
Answer final questions

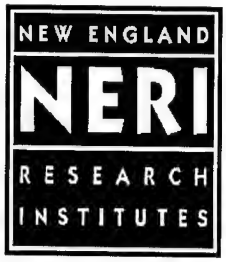
Training Schedule for SGBC1 Interviewers
Wednesday and Thursday, August 21 & 22, 1996

Wednesday, August 21

9:00 - 1:00 (Main Conference Room)	CHERYL CASWELL: Introduction to project and project staff
	MARY FOERTSCH: Communication with NERI
	DENNIS COHEN and RENEE BOSS Respond to trainees questions (re: pre-training review of the manual) QA plan and confidentiality View project tapes Go over the instrument
	DENNIS COHEN AND RENEE: BOSS: Mock interview
1:00 - 2:00	LUNCH
2:00- 4:30	DR. KAREN FREUND: Breast Cancer issues and terminology

Thursday, August 22

9:00 - 12:00 (TBA)	DENNIS COHEN & RENEE BOSS: De-brief mock interview
	DENNIS COHEN, RENEE BOSS , & RITA MCNALLY: Conduct practice interviews
	DENNIS COHEN, RENEE BOSS, & RITA MCNALLY: Feedback on practice interviews
12:00 - 1:00	LUNCH
1:00 - 5:00	DENNIS COHEN, RENEE BOSS, SUSAN MCDERMOTT, AND DR. VOULA OSGANIAN: Conduct mock interviews
	DENNIS COHEN & RENEE BOSS: Feedback on interviews and final questions



Physician Decisions in Breast Cancer Care

Status of Physician Recruitment

CALIFORNIA

Race	Specialty	Year of Grad.		Identification #		Interview Complete	
		Male	Female	Male	Female	Male	Female
African-American	General Surgeon	1980		301166		✓	
Caucasian	Medical Oncologist	1979		311108			
Caucasian	General Surgeon	1971	1973	300393	303072	✓	
Caucasian	General Surgeon	1980	1979	301316	307474		✓
Caucasian	General Surgeon	1982	1983	304355	312474		✓
Caucasian	Medical Oncologist	1983	1982	311266	302196		✓
Caucasian	General Surgeon	1975	1974	305287	312900		✓
Caucasian	Medical Oncologist	1987	1987	303015	303377		✓
Caucasian	Medical Oncologist	1980	1980	306913	312449		
Caucasian	General Surgeon	1976	1976	302072	313026		
Caucasian	General Surgeon	1978	1978	302851	312917		
Caucasian	General Surgeon		1989		300148		✓
Caucasian	General Surgeon		1985		306116		✓
Caucasian	General Surgeon		1982		301150		✓
Caucasian	Medical Oncologist		1970		303800		✓
Caucasian	General Surgeon		1981		312757		✓
Caucasian	General Surgeon		1977		305540		✓
Caucasian	General Surgeon		1991		100838		✓
Caucasian	General Surgeon		1975		313046		✓
Caucasian	Medical Oncologist		1974		312033		✓
Caucasian	General Surgeon		1986		311882		✓
Caucasian	General Surgeon		1984		313049		✓
Caucasian	General Surgeon		1983		313036		✓
Caucasian	General Surgeon		1991		313001		
Caucasian	General Surgeon		1988		313047		✓
Caucasian	General Surgeon		1980		313041		
Caucasian	General Surgeon		1981		313044		✓
Caucasian	General Surgeon		1983		310754		
Caucasian	General Surgeon		1982		304153		
Caucasian	Medical Oncologist		1984		304637		
Caucasian	Medical Oncologist		1974		308941		
Caucasian	General Surgeon		1986		305116		

GEORGIA

Race	Specialty	Year of Grad.		Identification #		Interview Complete	
		Male	Female	Male	Female	Male	Female
Caucasian	General Surgeon	1950		106109		✓	
Caucasian	General Surgeon	1946		102384			
Caucasian	Medical Oncologist	1964		101931		✓	
Caucasian	Medical Oncologist	1983		100376		✓	
Caucasian	General Surgeon	1974		100856		✓	
Caucasian	General Surgeon	1983		101175		✓	
Caucasian	General Surgeon	1963		100696		✓	
Caucasian	General Surgeon	1975		101136		✓	
Caucasian	Medical Oncologist	1976	1975	105135	108253	✓	✓
Caucasian	Medical Oncologist	1984	1986	103875	108254	✓	
Caucasian	General Surgeon	1986	1984	101881	103542	✓	✓
Caucasian	General Surgeon	1988	1988	103833	103549	✓	✓
African American	General Surgeon	1985	1983	103620	106774		✓
Caucasian	Medical Onclolgist		1969		106192		
African-American	General Surgeon		1977		108251		
African-American	Medical Oncologist		1974		100110		✓
African-American	General Surgeon		1982		108155		✓
African-American	Medical Oncologist		1985		102684		✓
Caucasian	Medical Oncologist		1970		107378		✓
African-American	General Surgeon		1989		104862		✓

MICHIGAN

Race	Specialty	Year of Grad.		Identification #		Interview Complete	
		Male	Female	Male	Female	Male	Female
Caucasian	General Surgeon	1948		200111		✓	
Caucasian	Medical Oncologist	1977		201657		✓	
Caucasian	General Surgeon	1984	1984	203199	206017		✓
Caucasian	General Surgeon	1978	1978	200299	209157	✓	✓
Caucasian	General Surgeon	1977	1977	200070	203685	✓	✓
Caucasian	Medical Oncologist	1973	1972	204378	209007		✓
Caucasian	General Surgeon	1981	1981	206931	207390		✓
Caucasian	General Surgeon	1979	1980	200947	203806	✓	✓
Caucasian	General Surgeon	1983	1984	206383	202815		
Caucasian	General Surgeon		1970		209401		✓
Caucasian	Medical Oncologist		1989		209610		✓
Caucasian	General Surgeon		1988		208279		✓
Caucasian	General Surgeon		1986		209619		
Caucasian	General Surgeon		1979		209609		
Caucasian	General Surgeon		1989		206676		
Caucasian	General Surgeon		1970		209618		
Caucasian	Medical Oncologist		1983		209606		
Caucasian	Medical Oncologist		1980		209603		
Caucasian	Medical Oncologist		1988		205164		
Caucasian	General Surgeon		1986		207509		✓

SUMMARY

	SCHEDULED	INTERVIEWED	TOTAL
CALIFORNIA	20	21	41
GEORGIA	5	20	25
MICHIGAN	12	15	27
ALL STATES	37	56	**93**

Precision and power of experimental design to detect differences in prevalence of binary endpoint.

Response probability	Standard error*
0.100	0.022
0.250	0.031
0.500	0.036
0.750	0.031
0.900	0.022

Independent variable	Parameters		Detectable difference (%)**
Physician's sex†	*Disagreement* (%)		
	5		7
	10		9
	15		11
	25		14
	50		20
	Reference subjects (%)	*Reference prevalence* (%)	
Patient characteristics§	50	10	+17
		25	−17, +21
		50	−21, +21
Physician covariates§	25	10	+21
		25	−18, +24
		50	−24, +24
	10	10	+33
		25	−22, +36
		50	−33, +33

*Based on binomial distribution, n = 192 physicians.
**80% power, 5% Type I error.
†96 paired interviews. §192 total interviews divided as indicated.

BOSTON UNIVERSITY SCHOOL OF MEDICINE

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PHYSICIAN DECISIONS IN BREAST CANCER CARE

INFORMED CONSENT

Recent work on physician preference suggests that while this process is guided by medical criteria, other considerations also influence physicians. The purpose of this research study is to identify which factors are operative in physician's decisions and what implications arise as a result.

Physicians asked to participate in this study are randomly selected from mailing lists developed from the membership of professional societies and other sources. At this time, we would like to encourage your cooperation in this research endeavor.

Your involvement in this study is two-fold. First, we will present you with two videotaped simulated doctor-patient encounters, which we would like you to consider and render diagnostic and treatment recommendations. Each evaluation should take no more than 5-7 minutes to view. Second, a senior member of our interviewing staff will conduct a brief interview with you so that we might learn a little about you personally and professionally. This interview should take no more than 50 minutes to complete. The total of your time involvement will be approximately one hour. At any time you may refuse to answer questions or withdraw from the study.

We recognize that most clinicians are extremely busy. As such, we will make special efforts to carry out the data collection at times and in places which are convenient to each participating physician.

All precautionary measures will be taken to ensure subject confidentiality and privacy. All data (from interviews and simulation evaluations) will be safely secured in locked cabinets, and access to this data will be restricted to the Principal and Co-Principal investigators. All data will be published in aggregate form only. To ensure high quality data, the interview will be audiotaped for later review by project staff. The tapes will also be secured in locked cabinets, and they will be erased after they are reviewed.

IRB 12/18/95

Research Staff Initials_____ Physician Initials_____

Date_____ Date_____

There are no foreseeable risks or discomforts associated with your participation in this research. It is hoped that, as a result of this study, we will be able to understand more fully the factors taken into account by physicians in reaching diagnostic and therapeutic decisions. With the knowledge, we hope that future efforts can be directed at rationalizing the clinical decision-making process. You also will be paid $100 at the completion of the interview.

Representatives from the U.S. Army Medical Research, Development, Acquisition and Logistics Command are eligible to inspect the records of this research as a part of their responsibilities to protect human subjects in research.

If you have any questions regarding the research or your participation in it, either now or at any time in the future, please feel free to ask them. The research team, particularly Karen Freund, M.D., who may be reached at 617-638-8030, will be happy to answer any questions you may have. You may obtain further information about your rights as a research subject by calling the Coordinator of the Institutional Review Board for Human Research of Boston University Medical Center at 617-638-7266. If any problems arise as a result of your participation in this research, including research-related injuries, please call the principal investigator, Karen Freund, M.D., at 617-638-8030 immediately.

You are not obligated to participate in this research. If you choose not to participate, your present and/or future standing in the medical community will not be affected in any way. Also, if you participate, you may withdraw your consent and discontinue participation at any time without affecting you in any manner.

It is hoped that you will agree to participate in this research, by signing this informed consent form in the space provided. Your help is vital to the success of this study. If you have any questions concerning this study, please feel free to contact one of the following:

Karen M. Freund, M.D., M.P.H.
Principal Investigator
(617) 638-8030

John B. McKinlay, Ph.D.
Co-Principal Investigator
(617) 923-7747

VALID FOR USE THROUGH 12/18/96
PER IRB 2NF 12/18/95

Research Staff Initials_____

Date_____

Physician Initials_____

Date_____

SUBJECT'S STATEMENT OF CONSENT

You are authorized all medical care for injury or disease which is the proximate result of your participation in this research. Other than medical care that may be provided and the $100 professional fee, you will not receive any compensation for your participation in this research study; however, you understand that this is not a waiver or release of your legal rights.

I have read the above description of this research study, and I understand it. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I understand that I will receive a copy of this form.

I understand that I am free to withdraw this consent and discontinue participation in this research study at any time without prejudice.

I voluntarily consent to my participation in the described research study.

_____	_____
Signature of Physician	Signature of Research Staff
_____	_____
Printed Name of Physician	Printed Name of Research Staff
_____	
Address	
_____	_____
	Date

Research Staff Initials_____ Physician Initials_____

Date_____ Date_____